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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 2939717

April 2, 1997

Won Ok Oh
President
Bio-Life International Corp.
18820 Cox Avenue
Saratoga, CA 95070

WARNING LETTER

Dear Ms. Oh:

This letter is written in reference to your firm's marketing and distribution of the product BIO-OXY. Your promotional brochure (labeling) titled, "BIO-OXY, DRINK OXYGEN & FEEL THE DIFFERENCE" includes numerous therapeutic claims for BIO-OXY which cause the product to be a drug (Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Objectionable claims include the following:

> "Orally and topically for burns, abrasions, and allergic reactions"; "anti-inflammatory, broad spectrum bacteriocidal, fungicidal as well as viricidal agent"; "effective against all viruses tested;" "human retro-virus;" "inactivating Herpes viruses;" "inhibitory to Saccharomyces species"; "inhibitory to C. albicans;" "diarrhea"; "sunburns, cuts;" "sore throat, cold and flu;" "cold sores, hives, athletes foot;" and "alleviate the pain of toothache."

Since this drug is a "new drug," it may not be marketed in the U.S. without an approved new drug application (Section 505(a) of the Act).

This drug is also misbranded (Section 502(f)(1)) because its labeling fails to bear adequate directions for use for the condition for which it is offered and because its labeling is false

and misleading since it suggests that there is evidence to establish that BIO-OXY is safe and effective for its labeled uses, when in fact, this is not the case (§ 502(a) of the Act).

Some of the claims for BIO-OXY cited above cause it to be subject to the final rules of several OTC drug products (monographs), such as, fungicidal and athletes foot claims which come under the Topical Antifungal Drug product (Part 333, Subpart C) and allergic reaction claims which come under the Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use (Part 341). The monographs are found in Title 21 Code of Federal Regulations (21 CFR). Neither the formulation nor the labeling for the product conform to these final regulations.

Since the labeling for BIO-OXY also recommends use of the product on pets, stating, "It is good for them as it is for you.," the drug is adulterated under Section 501(a)(5) in that it is a new animal drug which is unsafe within the meaning of Section 512 of the Act.

BIO-OXY labeling also recommends use of the product in sterilizing hospital equipment and instruments, which cause it to be a device (Section 201(h) of the Act). BIO-OXY is a misbranded device under Section 502(o) of the Act in that it is manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510, is not included in a list required by Section 510(j), and a notice or other information respecting the device has not been provided to the FDA as required by Section 510(k).

Additionally, the "PROFESSIONAL PRICE LIST" (labeling) under the heading "PRODUCT DESCRIPTION" includes objectionable claims for a number of other products offered by your firm. These claims include:

BEE POLLEN - inhibit the release of histamine and decrease allergenic response.
BEE PROPOLIS 5X Concentrate - anesthetic properties and exerts bacteriostatic and bacteriocidal effects on many gram positive and gram negative micro-organisms and speeds the development of granulation when applied topically to burn wounds.
PYCNOGENOL - anti-inflammatory effect.
FREEZE-DRIED FEVERFEW - preventing migraine attacks.
PRIME GUGGULU POWER - obesity, decreases LDL Cholesterol and Triglycerides while increasing HDL, hyperlipidemia.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, San Francisco District Office, attention: Marshalette Edwards, Investigator.

Sincerely,

Patricia C. Ziobro
District Director
San Francisco District